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The purpose of this project is to conduct cost-effectiveness analyses (CEA) of three treatment alternatives (modified radical mastectomy, breast conserving surgery with radiation therapy, and breast conserving surgery without radiation therapy) for elderly women (67 and older) with early stage breast cancer. Data for the CEA will be obtained from surveys of breast cancer patients at three, four, and five years post-treatment, their surgeons, and Medicare's National Claims History File. (Data for women up to two years post-treatment will be obtained from a complementary research project.) Both national physician and patient surveys were begun during the last year. Preliminary results indicate that over fifty percent of elderly women treated for early stage breast cancer during 1992-1994 received breast conserving survey. However, there are still wide geographic variations across the U.S.

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FOREWORD

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Jack Hadley Sept. 26, 1997
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I. INTRODUCTION

A. Nature of the Problem and Background

In 1994, 183,000 women developed breast cancer and 47,000 women died of the disease. Forty-four percent of the new cases and 56 percent of the deaths occurred among the 13 percent of the female population which was 65 or older. Thus, more than 80,000 elderly women are diagnosed with breast cancer each year and, based on increased use of screening examinations, upwards of 70 percent of these women should be diagnosed in local stages (Tabar et al., 1985).

As a consequence of this high burden of disease, the elderly incur a disproportionate share of the $35 billion in annual direct medical costs of cancer in the U.S. In addition, the cost of medical care to the Medicare program for breast cancer survivors is substantial. On average, breast cancer survivors live an additional 11.2 years and incur almost $54,000 in Medicare costs (Riley et al., 1995). Despite the enormous resources expended on cancer care, little is known about the financial impact of alternative cancer therapies.

Randomized clinical trials of breast cancer therapies conducted in the 1980s have demonstrated that breast conserving surgery (BCS) with radiation therapy (RT) yields equal survival to modified radical mastectomy (MRM) (Bader et al., 1987; Fisher et al., 1985; Fisher et al., 1989). However, few elderly women were included in those trials. Further follow-up of women in the trials indicates that survival rates for local stage disease continue to be equivalent for both treatment modalities, whether or not BCS is accompanied by RT (Early Breast Cancer Cooperative Group, 1995; Fisher et al., 1995). However, local recurrence rates are 30% higher in women who did not receive RT in conjunction with BCS compared to BCS with RT. Although age was not considered a contraindication to either treatment modality (Steinfeld et al., 1989; Balducci et al., 1991), there has been very little direct analysis of the effects of alternative treatment choices on survival or recurrence in the elderly.

In spite of the evidence from clinical trials, the use of BCS by elderly patients varies greatly and appears to be under-used. Estimates from the late 1980s indicate that only 3.5% to 21% of elderly women received BCS; fewer than half of these women received RT (Chu et al., 1987; Yancik et al., 1989; Silliman et al., 1989; Lazovich et al., 1991; Bergman et al., 1991; Farrow et al., 1992; Nattinger et al., 1992; Newcomb and Carbone, 1993). Numerous other studies have documented additional age-related variations in breast cancer treatment (Greenfield et al., 1987; Samet et al., 1986; Silliman et al., 1989; Chu et al., 1987; Lazovich et al., 1991; Bergman, et al., 1991; Farrow et al., 1992), including less aggressive use of intravenous adjuvant chemotherapies (Newcomb and Carbone, 1993; Silliman et al., 1989; Allen et al., 1986; Chu et al., 1987), despite similar rates of toxicities seen in younger patients (Begg and Carbone, 1992), and fewer consultations with medical or radiation ecologists in elderly compared to non-elderly women (Newcomb and Carbone, 1993).

The few cost-effectiveness analyses that have examined treatment of local breast cancer have focused on younger women (Smith and Hillner, 1993), and/or have used data from RCTs (Smith and Hillner, 1993; Hillner and Smith, 1991; Verhoef et al., 1991). The efficacy of treatment and cost observed under RCT conditions are not likely to replicate those expected in actual clinical practice, where the populations are more heterogeneous and treatments less intense (Eisenberg, 1989; Drummond and Davies, 1991; Smith, Hillner, and Desch, 1993). This concern may be particularly germane when addressing the elderly, because of their substantial diversity in health, functional status, and social support. In addition, few breast cancer trials have included elderly women, especially those aged 75 or more. Munoz and colleagues, using 1983-1984 charge data for a case series of 79 women treated in one hospital found BCS and RT to be 37% more expensive than MRM; however, surgeons' fees were 55% higher for the MRM than for the more conservative surgery (1986).

B. Goals and Methods of Approach

The goal of this project is to conduct cost-effectiveness analyses of three treatment modalities for breast cancer (MRM, BCS with RT, and BCS without RT) in elderly women with local disease. Benefits will be based on survival and quality of life measured annually up to five years post-treatment. Costs will be measured from the social perspective and will be based primarily on the direct costs of all medical care. Secondary analyses will consider various substrata of women, based on age (67-75, older than 75), initial health state (derived from comorbidities at time of diagnosis and prior medical care use), place of residence (urban or rural), marital status and living arrangement at time of treatment (alone, with spouse, with others), and hospital type (cancer center, other teaching hospital, nonteaching)

Actual practice may deviate from recommended guidelines for several reasons: elderly women's poorer health generally, preferences and quality of life assessments, fewer social supports, diminished socioeconomic status, transportation difficulties, and poorer access to high-volume breast cancer surgeons and radiation therapy centers. Prior research, which has typically examined only one or two of these elements and has not focused primarily on elderly patients, provides few insights on these questions. By conducting cost-effectiveness analyses that take these factors into account, the proposed project will assess whether elderly women, generally or in particular circumstances, are receiving sub-optimal patterns of care. If they are, our analyses of treatment choice determinants and of the relationship between treatments and outcomes will generate recommendations for policy changes to alter treatment patterns, as well as to provide information for developing clinical guidelines regarding preferred treatment choices under a variety of patient and environmental circumstances.

Data will be collected by telephone surveys of a nationally representative sample of 2,000 Medicare beneficiaries who were treated for local breast cancer between 1992 and 1994, and of

their surgeons. The patient and physician samples will be drawn from Medicare's 5% Standard Analytic File, which is a nationally representative random sample of all Medicare beneficiaries and the physicians who treated them. In order to obtain a final sample of 2,000 women, we are contacting approximately 5,000 physicians in order to request information on over 10,000 beneficiaries. The combination of physician nonresponse, patient ineligibility, and patient nonresponse will result in the final sample of 2,000 patients.

The physician survey is being administered by mail with telephone follow-up in two phases: Physicians will be surveyed in order to verify that the patient in fact had breast cancer and to determine the stage of disease. Women with late stage (III or IV) disease are not eligible for the analysis. Women identified as eligible will then be surveyed by telephone to obtain information on current health and basic sociodemographic characteristics. In Phase 2 of the physician survey, the physicians of women who completed interviews will be administered a brief mail survey (with telephone follow-up) to obtain information about their propensities to choose breast conserving surgery and radiation therapy. These propensities are derived from responses to three hypothetical case scenarios.

Medical care use data will come from the Medicare National Claims History file for all respondents, nonrespondents, and decedents. (Cost data for decedents will be used in calculating cost-effectiveness ratios.) The relationship between treatment and outcomes will be estimated using an approach to correct for bias due to the observational nature of the data.

Data for women who are up to two years post-treatment will come from a complementary project (Care, Costs, and Outcomes of Local Breast Cancer, AHCPR Grant No. HS08395), which is supporting the collection of data for approximately 750 breast cancer patients who are being followed prospectively for up to two years. (The costs of the national physician and patient surveys are being shared by the two projects.)

Cost-effectiveness analysis will be used to combine the costs and outcomes of treatment over the five year evaluation period. Cost-effectiveness ratios will be constructed based upon the formula $CER_t = \Sigma\ Costs_t / \Sigma\ QALYs_t$ where t=treatment modality (MRM, BCS w/RT, BCS w/o RT). Costs are calculated from Medicare claims and QALYs are calculated from five-year survival curves for each of the three treatment outcomes and patient preference assessments (based upon adjusted patient EuroQol© scores) at approximately years 1, 2, 3, 4, and 5. Preference assessments for time periods between measurements will be interpolated linearly, or extrapolated on a patient age-adjusted basis. We will then divide the treatment survival curve for each of the three therapies into five 12 month segments. We will multiply the average patient months of survival for each portion of the survival curve by the average preference weight for that time period to develop a measure of the total preference-adjusted survival months for each segment of the survival curve. The number of QALYs for each of the three therapies will be taken as the discounted sum of the preference-adjusted survival months of the five curve segments. This method will account for survivor bias in responses to the preference instruments because we will include all patients in the calculations, with patients who die having a preference weight of 0 from the date of death to the end of the observation period.

II. PROGRESS DURING YEAR THREE

A. Analysis of State Hospital Discharge Data

Two preliminary analyses of breast cancer treatment choice using individual hospital discharge data from five states for 1988 and 1991 were completed. One manuscript was published in the *Papers and Proceedings of the Annual Meeting of the American Economic Association* and the other has been accepted for publication by *Inquiry.* The former manuscript, "The Effect of Insurance Coverage on Breast Cancer Patients' Treatment and Hospital Choices," examines the

interrelationship between type of insurance coverage, the choice of a hospital (the nearest cancer hospital vs a more-distant hospital), and treatment choice (breast conserving surgery (BCS) vs mastectomy). The results indicate that the hospital choice and treatment choice decisions are jointly made, in that women who choose BCS are more likely to receive treatment in a more-distant cancer center and vice-versa, while women who bypass the nearest cancer hospital are more likely to receive BCS. Moreover, when treatment at the nearest cancer hospital is foregone, the actual treatment hospital tends to be larger than the nearer hospital. The analysis also found that women with HMO insurance coverage, Medicaid coverage, or no insurance coverage were less likely to receive BCS. Finally, distance to the nearest cancer hospital had a significant negative effect on the probability of bypassing that hospital, i.e., women who live farther away are less likely to bypass. (This paper was also selected for both poster and platform presentation at the Era of Hope Conference scheduled for November 1997.)

The second manuscript, "Breast Cancer Treatment Choice and Mastectomy Length of Stay: A Comparison of HMO and Other Privately Insured Women," analyzed the treatments and length of stay separately for each of the states for which hospital discharge data were available. The results indicate that on average women covered by HMOs were less likely to receive BCS (relative odds = 0.93) and the length of stay for mastectomy patients covered by HMOs was significantly shorter, whether measured by average days (0.2 days less) or the relative odds of a very short stay of 1 or 2 days (relative odds = 1.21-1.29). Short stays for mastectomy patients were much more common in California than in the other four states in the analysis.

B. National Physician Survey

1. Pilot Survey

A pre-test of alternative approaches to conducting the physician survey was conducted in the first quarter of 1997. A sample of 198 surgeons was drawn from the national survey sample data base. The sample cases were distributed among four cells, which varied by the amount of financial incentive, $15 vs $25, and by whether the physician survey form was included along with the request for information about patient eligibility. The primary purpose of the pilot was to test whether surgeons would provide information about specific patient's eligibility for the planned national patient survey without having obtained prior consent from the patient to contact the surgeon. Eligibility determination requires confirming that the sample patient in fact had breast cancer and that the disease was early stage.

Following HCFA regulations, surgeons were first sent a letter from the HCFA Administrator informing them of the study and telling them that their cooperation is completely voluntary and is not related in any way either to their Medicare payments or to any official administrative matters. One week after sending this letter, surgeons were mailed a packet containing a cover letter from the Principal Investigators, an endorsement letter from the American College of Surgeons, a patient eligibility form, and, depending on which cell the physician was assigned to, a check for either $15 or $25, and, in half the cases, the same survey instrument used for to obtain propensity and other information from cohort surgeons. Cell assignment was random. However, the pilot was limited to surgeons who have only one patient in the national patient sample.

Table 1 reports the results of the pilot test. Overall, 129 surgeons, 65.2%, completed the survey. This is an extremely good response rate, especially in light of the fact that no effort was made to obtain correct addresses for surgeons whose contact material was returned as "Not Deliverable" and that only 5 telephone attempts were made to contact surgeons who did not

respond by mail within two weeks. Normally, the survey firm, Mathematica Policy Research, conducts an aggressive search to obtain forwarding addresses and will make over 15 telephone calls (many of which result in busy signals or answering machine contacts) to obtain survey information from physicians. If the No Contact cases are excluded, the overall response rate increases to 72.9%, which is well within the acceptable range for physician surveys.

The amount of financial incentive had little effect on response. Not surprisingly, however, including the physician survey, which takes 15 to 20 minutes to complete, did appear to have a significant negative effect on the response rate, 64.4% compared to 81.6% for surgeons who were only asked to determine patient eligibility. Based on the eligibility information received, 55% of patients are eligible for the patient survey, 31% are ineligible, and no information was provided for 14%. A number of cases in the last category was due to the physician having moved and no longer having access to the patient's records. More thorough follow-up in the full survey will be able to resolve some of these cases.

2. Phase 1 Physician Survey to Determine Patient Eligibility

The national physician survey was implemented shortly after the completion of the pilot survey. The potential universe of 5,671 physicians was randomly allocated to three survey replicates for the purpose of efficient management of the survey. Replicates 1 and 2 have been fully released and are in the process of being completed. The fielding of replicate 3 is being held up pending the resolution of the first two replicates in order to determine how many additional physicians need to be surveyed in order to reach the target number of eligible patients for the patient interview.

Table 2 summarizes the results to date of Phase 1 of the national physician survey. So far, 2,081 cases have been resolved and another 1,419 cases are still pending or have not yet been contacted. Of the resolved cases, 14.4 percent could not be located, were deceased or retired, or no longer had access to the patients' records. Just over 85 percent completed patient eligibility forms for all or most of their patients in the sample. If just half of the pending cases complete the patient eligibility form (and assuming that 14 percent will be ineligible as above), then the projected completion rate for the first two replicates would be just over 70 percent, which is quite reasonable for physician surveys, especially considering the potential sensitivity of the information being requested.

The completed physicians' eligibility forms have enabled us to determine the eligibility for the national patient survey of 3,272 patients (approximately 1.8 patients per physician respondent). Of those patients, 53.2 percent have been determined to be eligible, i.e., to have early stage breast cancer as defined on the patient eligibility form. This figure is very similar to the eligibility rate for the prospective cohort portion of the larger project.

3. National Patient Survey

The national patient survey was begun with the first wave of patients identified as eligible by respondents to the physician survey. Women first receive a letter from the HCFA Administrator informing them of the study and that they are under no obligation to participate. This is followed by a second mailing which describes the study and informs them that they will be contacted by telephone. As shown in Table 3, 834 women have been contacted to date. Of those, 13.3 percent (111 cases) were determined to be ineligible for the reasons described in Table 3. Of the remainder, 65.7 percent (475 cases) have completed interviews. Since some proportion of the

pending cases are likely to be successfully completed, the preliminary experience suggests that a final response rate of 70 percent or higher is quite likely.

4. Obtain HCFA Data

A request was submitted to HCFA in July 1997 for all Medicare claims for women in the national survey sample for the period 1991 through the most recent year available (1996). These claims will be used to determine the treatment patterns (breast conserving surgery with or without radiation therapy, or mastectomy), costs, and prior medical care use for all sample cases. Respondents will be compared to nonrespondents to assess the possible presence and extent of nonresponse bias. Cost profiles will be constructed for up to four years post-treatment. An additional year of claims data will be requested in 1998, which will permit the construction of five-year cost patterns for women treated in 1992.

C. CONCLUSIONS AND PLANS FOR YEAR FOUR

The data collected so far from the national surveys provide preliminary information on the trend in the use of BCS among eligible elderly women. First, the physician survey responses indicate that approximately 55 percent of cases had early stage breast cancer (stages I, IIA, or IIB). This eligibility rate is comparable to the eligibility rate for the prospective cohort portion of the companion analysis, which is supported by AHCPR. That data base, which determines eligibility through pathology reports and physicians' review of the case, also has an eligibility rate of approximately 55 percent. The similarity between the studies suggests that neither is missing or omitting significant numbers of potentially eligible cases.

Second, it appears that the trend in the rate of BCS is increasing over time, but still has substantial cross-sectional variability. Preliminary tabulations of the rate of BCS over time are reported in Table 4, which indicate that the BCS rate for elderly women with early stage cancer increased from 51.3 percent in 1992 to 55.2 percent in 1994. (Prospective cohort data for 1996/97 suggest a BCS rate of almost 65 percent.)

Table 4 also shows how the rate of BCS varied across 3-digit zip code areas in 1994. These rates were constructed from all Medicare claims in 1994 for women who had either a breast cancer diagnosis or a breast surgery procedure code on a bill submitted to HCFA. The areas are limited to those that had at least 10 elderly women with a breast cancer diagnosis. However, staging information was not available. As the table shows, the average BCS rate was 26.7 percent, but it varied more that ten fold from a low of 4.5 percent to a high of 60 percent. (Note that this rate does not exclude late stage cases and, therefore, is lower than the estimates based in the patient survey.) Moreover, data collected from the prospective cohort sample between the last quarter of 1995 and the middle of 1997 also show substantial variation across the four geographic areas in that study, with BCS rates varying from 44 percent in Texas to 78 percent in eastern Massachusetts.

The reasons for these variations will be explored in the coming year. In particular, we suspect that physicians' treatment propensities based on hypothetical case scenarios may be related to these strong regional effects. Moreover, the existence of regional differences, which are probably not strongly related to differences in patients' underlying health conditions, should be very useful for implementing the instrumental variable statistical method for the analysis of observational data.

Analysis plans for year four, the final year of the project, call for completing the national patient survey and phase 2 of the national physician survey, calculating costs and constructing

measures of pre-treatment medical care, and estimating models of the determinants of treatment choice. The latter will be derived from preliminary work currently being done with data collected from the prospective cohort patients. The cost and pre-treatment measures of medical care use will be combined with information on patients' current health states and preferences to conduct the cost-effectiveness analyses for patients treated in 1992 through 1994. The results of these analyses will be used to assess whether elderly breast cancer patients' actual patterns of care are consistent with the cost-effective pattern of care. If not, then recommendations will be made based on the identification of factors that influence treatment choice.

Table 1

MD Pilot Data by Cell

	Cell 1 ($15)	Cell 2 ($15 + survey)	Cell 3 ($25)	Cell 4 ($25 + survey)	Total
Total Allocated	49	49	50	50	198
Not Contacted	3	4	9	5	21
Refusals: Total	8	17	5	12	42
Passive	7	14	4	10	35
Unknown Outcome	1	0	0	0	1
No MPR Contact	0	3	1	1	5
Language Barrier	0	0	0	1	1
Completions	38	28	33	30	129
Eligible	19	13	21	18	71
Ineligible	14	10	8	8	39
Other: Total	5	5	4	4	18
No Information	5	5	4	3	17
No Cancer	0	0	0	1	1
Response Rate[a]	82.6%	62.2%	80.5%	66.7%	72.9%

Note: a. Completions divided by Contacts (Allocated less Not Contacted).

Table 2

Interim Status of National Physician Survey

Physicians		
Total in Replicates 1 and 2	3,500	(100.0%)
Unassigned/Pending	1,419	(40.5)
Resolved	2,081	(59.5)
Resolved Cases	2,081	(100.0%)
Complete	1,778	(85.4)
Final Refusal	5	(0.2)
Unable to Locate/Deceased/Retired	209	(10.0)
Wrong Patient/No Access to Records	89	(4.4)
Resolved Patient Cases (from Physician Survey)		
Total	4,004	(100.0%)
Eligible	1,740	(43.5)
Not Eligible	1,532	(38.2)
MD Refused	14	(0.3)
MD Not Located/Deceased/Retired	399	(10.0)
MD Does Not Have Records	319	(8.0)

Table 3

Interim Status of National Patient Survey

Total Interviews Attempted		834 (100.0%)
Eligible and Complete		475 (57.0)
Total Pending		248 (29.7)
Callback	52 (6.2%)	
No Answer/Answer Machine	53 (6.4)	
Wrong Number	41 (4.9)	
Initial Refusal	81 (9.7)	
Ill	4 (0.5)	
Other	17 (2.0)	
Ineligible		111 (13.3)
Deceased	45 (5.4)	
Impaired/Ill/Nursing Home	52 (6.2)	
Language Problem	3 (0.4)	
Prior Breast Cancer	3 (0.4)	
Advanced Stage	2 (0.2)	
No Breast Cancer	6 (0.7)	

Table 4

Preliminary Estimates of BCS Rates,
Over Time and Cross-Sectional

Over Time[a]	Rate (N)	
1992	51.3%	(236)
1993	53.4	(251)
1994	55.4	(172)
Cross-Sectional, 1994 (3-digit Zip Code Areas)[b]		
Low	4.5%	
10th Percentile	15.6	
25th Percentile	20.4	
Median	26.1	
Mean	26.6	
75th Percentile	32.7	
90th Percentile	38.1	
High	60.0	

Notes: a. From preliminary data from National Physician Survey eligibility forms.

b. From 1994 HCFA claims for women with a breast cancer diagnosis; no stage information available.

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